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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S REPLY IN SUPPORT OF ITS MOTION TO EXCLUDE THE OPINIONS OF REBECCA BETENSKY, PH.D.

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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INTRODUCTION

There is no dispute Dr. Betensky did not account in any way for nearly a decade of data for the Simon Nitinol Filter ("SNF") prior to 2000. Nor is there any dispute that Dr. Betensky admitted this failure could invalidate her opinions entirely. Plaintiffs do not argue that Dr. Betensky did not mean what she said. Plaintiffs do not argue that Bard somehow misquoted her admission or characterized it in a false light.

The impact of Dr. Betensky's concession left Plaintiffs grasping at straws, and their response was as confusing as it was unfounded. For the first time in their opposition brief, and with no documentary evidence or support whatsoever, Plaintiffs falsely accused Bard of both refusing to produce the data at issue, and/or intentionally "hiding" it through some trick in an Excel spreadsheet. The allegations are patently false. As set forth below, Plaintiffs have had this data in multiple spreadsheets since 2013, including in a spreadsheet that Dr. Betensky used. Moreover, an elementary understanding of Excel would have revealed that the information was never "hidden." In any event, Plaintiffs *never* contacted Bard to inquire about these issues. Nor does Plaintiffs' eleventh-hour attempt to explain away the data through the testimony of *counsel* or another expert in their opposition brief change the fact that Dr. Betensky failed to consider anything prior to 2000. The lengths Plaintiffs are willing to go to distract from Dr. Betensky's admission only underscore that her opinions are inadmissible under *Daubert* and Rule 702.

Dr. Betensky's opinions are equally inadmissible for the independent reason that she admitted she could not rule out alternative explanations for the reporting risk ratio ("RRR") she calculated. Specifically, Plaintiffs do not address Dr. Betensky's admission that she did not account for, let alone rule out, the possibility that differences in the way asymptomatic adverse events are detected between the SNF and retrievable filters could account for her findings. Nor do they contest Dr. Betensky's failure to account for the potential that adverse events for the retrievable devices were subject to increased reporting because of litigation notoriety that did not impact the SNF.

For these reasons, and as set forth more fully in Bard's Motion and the reply

below, the Court should exclude Dr. Betensky.[1]

ARGUMENT

I. Dr. Betensky's Failure to Consider Pre-2000 SNF Data Admittedly Invalidates Her Opinions.

As detailed in Bard's Motion, Dr. Betensky's failure to consider the first ten years of adverse event reports and sales data for the SNF is fatal to her analysis. (*See* Mot. at 10-11.) Plaintiffs retained Dr. Betensky to opine that Bard's retrievable filters have a higher risk of adverse events than Bard's SNF. (*See id.* at 4.) To do so, she compared the proportions of adverse event reports for the various retrievable filters over sales to the proportions of adverse event reports for the SNF over SNF sales. But, instead of considering all of the adverse event reports and sales data for the SNF starting from its product launch, as she had done for each of the retrievable filters, she only utilized SNF data that post-dated 2000. (*See* Ex. C, MDL Dep. Tr., 124:18-22; 125:20 to 126:2.) She did so even though she was aware that "the SNF was launched in 1990." (Ex. A, MDL Rep. at 13.) Dr. Betensky's failure to include this decade-long span of adverse event and sales data for the SNF is fatal to her analysis because she has no idea how many adverse events were reported for the SNF in the ten years she missed. Recognizing the significance of the data she failed to consider, Dr. Betensky further admitted, as she must, that "if I had had the data for the first ten years, I would have used it." (Ex. C, MDL Dep. Tr., 189:21-22.)

Dr. Betensky admitted that it is entirely possible she would not have estimated *any* increased risk of adverse events for the removable filters had she considered all of this SNF data, as she had done for each of the retrievable filters. Her testimony bears repeating here:

[1] Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable Arguments In Opposition To Bard's Motions To Exclude Plaintiffs' Experts Under Rule 702 And *Daubert* (Doc. 7799). Plaintiffs' Omnibus Statement is not directed at any specific *Daubert* motion Bard filed. As such, Bard does not respond to the Omnibus Statement but instead will address any necessary issues in the context of its individual *Daubert* replies.

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> Q. Because you didn't have data for adverse events for SNF prior to 2000 and you didn't have sales data for SNF prior to 2000, there's no way for you, as you sit here today, to say that if you had that data and calculated reporting risk ratios perhaps the reporting risk ratios would be greater for SNF over removable, maybe they'd be lower. You just don't know one way or another, right?
>
> A. I don't have the data so I don't know what the number would be if I had had the data. It could go -- like you said, I could get -- I could have gotten RRs that are larger than what I got. I could have gotten RRs that are smaller than what I got.

(*Id.* at 122:1-13.)[2]

It goes without saying that Plaintiffs' counsel cannot testify, and their interpretation of data Dr. Betensky failed to consider in no way salvages her report. It is equally the case that Dr. Eisenberg, who is not offered as a biostatistician in this case, cannot remedy Dr. Betensky's failure to consider this critical data.[3] The Court's inquiry is limited to what Dr. Betensky did, and did not, do.

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[2] Plaintiffs attempt to limit the relevant pre-2000 SNF data solely to events that post-date April 28, 1995, the date FDA cleared the "1995 version of the SNF," because this version "was the predicate to the Recovery filter, so the Recovery and each subsequent filter was based on the [1995] SNF." (Pls. Br. at 3, 13 n.16.) They argue that data "prior to this date are not relevant to the comparison." (*Id.* at 13 n.16.) Plaintiffs' argument is invalid for two reasons. First, the 1995 SNF is the same device as the pre-1995 SNF. Second, Plaintiffs' argument is completely contrary to the position that they have taken throughout this litigation. Plaintiffs now seek to sever the predicate chain starting at the 1995 version of the SNF, but continue that chain forward linking each subsequent filter back to that 1995 SNF. If, as Plaintiffs argue, the 1995 SNF data is relevant to a comparison of Denali® data because, down the predicate chain, the Recovery® was based off the SNF (Denali® is based off the Eclipse®, which is based off the G2®X, which is based off the G2® Express, which is based off the G2®, which is based off the Recovery®, which is based off the 1995 SNF), then, by their own logic, the pre-1995 SNF data should be equally relevant, because the 1995 SNF is based off of that pre-1995 predicate SNF. Plaintiffs' self-serving severance in this one instance is inconsistent with the position they have taken throughout this litigation, and is without merit.

[3] Furthermore, as Dr. Eisenberg's new opinions were not set forth in his Rule 26(a)(2)(B) expert reports, and as Bard did not elicit these new opinions at deposition, (*see* Ex. C, MDL Dep. Tr., 116:1-13), he should not be permitted to testify regarding this belated review. (*See* Case Management Order No. 8, § I.6 (Doc. 519).)

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A. The Record Flatly Disproves Plaintiffs' False Accusations Of Discovery Abuse.

Unable to contest the merits of Bard's argument, Plaintiffs falsely accuse Bard of discovery abuse. Specifically, Plaintiffs argue that Dr. Betensky was "prevented from considering" pre-2000 SNF data "because Bard refused to produce it." (Pls. Br. at 13, 14.) Plaintiffs' accusation is devoid of any support. They point to no letter, email, phone call, or conversation to corroborate their baseless claim. Nor could they, because this accusation is simply untrue.

Bard produced no less than twenty-four native, Excel spreadsheets containing pre-2000 SNF data.[4] All of these spreadsheets were produced in or before October 2016, four to five months before Dr. Betensky submitted her expert report. (*See* Ex. A, MDL Rep.) More importantly, most of these spreadsheets were produced to Plaintiffs in early 2013, years before the MDL was formed.[5] This data was available to Plaintiffs and thus equally available for Dr. Betensky's analysis. Indeed, Plaintiffs ultimately contradict themselves, admitting as they must that they "have access to some of these data." (Pls. Br. at 13.) Significantly, Plaintiffs admit that the pre-2000 SNF data was contained in one of the spreadsheets that "Dr. Betensky relied on . . . in forming her opinions." (*Id.* at 15 (citing BPVE-01-01054793).)

Plaintiffs next accuse Bard of somehow "hiding" this data in the Excel

[4] The spreadsheets were produced at the following Bates numbers: BPVE-01-01054793; BPVE-01-01073574; BPVE-01-01074470; BPVE-01-01074662; BPVE-01-10175227; BPVE-01-01075796; BPVE-01-01076261; BPVE-01-01496039; BPVEFILTER-01-00041441; BPVEFILTER-01-00050487; BPVEFILTER-01-00173992; BPVEFILTER-01-00174350; BPVEFILTER-01-00174368; BPVEFILTER-01-00202705; BPVEFILTER-30-00363193; BPVEFILTER-30-00363196; BPVEFILTER-30-00363201; BPVEFILTER-32-00000003; BPVEFILTER-32-00000009; BPVEFILTER-35-00084821; BPVEFILTER-35-00084822; BPVEFILTER-35-00084823; BPVEFILTER-35-00084824; and BPVEFILTER-35-00084825. (*See* Assorted Transmittal Letters, attached hereto as Exhibit J.)

[5] The spreadsheets produced in 2013 include: BPVE-01-01054793; BPVE-01-01073574; BPVE-01-01074470; BPVE-01-01074662; BPVE-01-10175227; BPVE-01-01075796; BPVE-01-01076261; BPVE-01-01496039; BPVEFILTER-01-00041441; BPVEFILTER-01-00050487; BPVEFILTER-01-00173992; BPVEFILTER-01-00174350; BPVEFILTER-01-00174368; and BPVEFILTER-01-00202705. (*See id.*)

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spreadsheets. (*See id.* ("Dr. Betensky relied on this spreadsheet in forming her opinions (Ex. 1, at 1), but the SNF data before 2000 was hidden in the electronic file by Bard and only recently discovered.").) First, Plaintiffs never claimed anything was wrong with these documents throughout the discovery process. They never subsequently indicated that anything was "hidden." (*Id.*) Plaintiffs claim to have "only recently discovered" allegedly "hidden" data after Bard moved to exclude Dr. Betensky. (*Id.*) Plaintiffs have had most of this data for over four years, including BPVE-01-01054793 identified above, which Bard produced on April 16, 2013. (*See* Ex. J.) Yet Plaintiffs did not advise Bard of any alleged discovery issue until filing their response brief.

Bard did not "hide" this data as Plaintiffs falsely claim. Bard produced these spreadsheets in their native format as required under Case Management Order No. 9, §II.B. (Doc. 1259). Certain of these spreadsheets, as they are kept by Bard in ordinary course of business, include data that is "filtered." This allows a user of the document to conduct comparison or analyses of subsets of the data in the spreadsheet. For example, the spreadsheet that Bard produced at BPVE-01-01054793 has a date restriction that filters out pre-2000 SNF data. However, anyone viewing the native spreadsheet can easily see, by looking at the numbered rows, that the non-filtered data starts at row 1695, effectively skipping rows 2 through 1694. Anyone familiar with Excel can easily remove the filters to view all of the data in the spreadsheet, including the pre-2000 SNF data.[6]

Finally, as demonstrated above, this was not the only spreadsheet with pre-2000 SNF data that was available to Dr. Betensky. Plaintiffs had twenty-three other spreadsheets available for her use, including four spreadsheets that did not have the pre-2000 SNF data filtered out.[7] Plaintiffs have had these four spreadsheets since 2013. (*See*

[6] To remove Excel filters and view all of the data at once, one need only select the "Sort & Filter" drop-down menu on the "Home" ribbon, then select "Clear." If the rows and columns are frozen, select the "View" ribbon, then select the "Freeze Panes" drop-down menu, and lastly select "Unfreeze Panes" (or "Freeze Top Row" to keep the top row visible while scrolling through the rest of the worksheet).

[7] The spreadsheets containing unfiltered SNF data were produced at the following Bates numbers: BPVE-01-01075796; BPVE-01-01076261; BPVE-01-01496039; and BPVEFILTER-01-00202705. (*See* Ex. J.)

Ex. J.) Therefore, Plaintiffs' accusations of discovery abuse are false, misleading, and only highlight the unreliability of Dr. Betensky's opinions.[8]

B. Bard's Internal Use Of Adverse Event Data Has No Bearing On the Admissibility Of Dr. Betensky's Opinions.

Plaintiffs argue that Dr. Betensky's opinions are somehow admissible because Bard and its consultant, Dr. Lehmann, allegedly conducted certain internal analyses of their own using adverse event data. (*See* Pls. Br. at 13.). Plaintiffs further argue that in claiming privilege over Dr. Lehmann's analysis, Bard represented that Plaintiffs' experts could attempt to replicate it using the same data. (*Id.*) Yet Bard never represented or conceded that any attempt to replicate such an analysis would survive a *Daubert* challenge. Aside from the fact that Plaintiffs have made no showing that Dr. Betensky and Dr. Lehmann conducted identical analyses, the purposes are entirely different. Plaintiffs would offer Dr. Betensky to opine to the jury that there is a higher risk of adverse events for the various retrievable filters over the SNF. As set forth above, her opinions are fatally flawed and a gross extrapolation from calculations she admitted were "crude." (Ex. B, Austin Dep. Tr., at 106:20-25.). Dr. Lehmann's analysis, however, was for internal use only and never intended for use in court. As such, it is not subject to *Daubert* and Rule 702.

Plaintiffs have cited no authority supporting their claim that Bard's internal analysis of adverse events somehow renders Dr. Betensky's opinions reliable under *Daubert*. (*See* Pls. Br. at 5-7, 13-14.) Plaintiffs' sole citation to *In re Gadolinium-Based Contrast Agents Products Liability Litigation*, No. 1:08 GD 50000, 2010 WL 1796334, at **2, 6 (N.D. Ohio May 4, 2010), is inapposite. The court in that case found the plaintiffs' expert testimony reliable because, among other reasons, the testimony related "to matters

[8] Plaintiffs attempt to further divert attention by discussing components of Dr. Betensky's report that Bard did not focus on. (*See* Pls. Br. at 2 n.1, 11.) Bard does not concede the reliability of those opinions. As Plaintiffs acknowledged, these opinions cannot be divorced from consideration of her RRR calculations. (*Id.* at 4, 11 ("cannot be taken in isolation" or "considered separately.") To the extent the Court determines her primary opinion on RRR is unreliable, her other opinions must be excluded as well.

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growing naturally out of research ***they*** [the experts] have conducted independent of this litigation." *Id.* at *6 (emphasis added) (citing Fed. R. Evid. 702 Advisory Committee Notes (2000 Amends.)). This case in no way stands for the proposition that a ***party's*** analysis of data independent of litigation bolsters the reliability of an opposing expert's opinion that purports to replicate that analysis. Dr. Betensky's opinions do not grow naturally out of research ***she herself*** has conducted independent of this litigation. *Id.* Instead, her analysis was performed solely for this litigation.

Furthermore, while Plaintiffs make much of the fact that, in addition to Bard, FDA, and authors in the medical literature utilize adverse event data, what they omit is determinative. As set forth in Bard's Motion, the FDA guidance is replete with cautions against the very use Plaintiffs advocate in this case. (*See* Mot. at 12-15; Ex. H, FDA Guidance at § IV(G).) Indeed, Dr. Thisted testified that, even though the guidance provides that comparison of adverse event reports "can be helpful in identifying possible trends, [] that same document goes on to describe the limitations of such things. It says, in particular, that because reporting to change over time because there can be differences in reporting rates for different drugs or different products, that they can't be relied upon for making causal comparisons between two products." (*See* Thisted Dep. Tr., 167:15-24, July 28, 2017, ("Thisted Dep. Tr.") attached as Exhibit K; *see generally* Ex. F, Thisted Rep.)

Finally, Bard was clear in its Motion that Dr. Betensky relied on reports "either made directly to Bard or that Bard retrieved from the FDA's [MAUDE] database." (Mot. at 4, 12.) FDA warns "MAUDE data is not intended to be used . . . **to compare adverse event occurrence rates across devices**." (Ex. D (emphasis added).) That is precisely how Dr. Betensky uses the data here. That companies conduct pharmacovigilance and analyze adverse event reports for certain internal purposes, which are not subject to *Daubert* or Rule 702, says nothing of the reliability of an expert witness's comparison of these data across devices for publication to a jury in federal court. FDA Guidance demands that such improper comparisons be "viewed with extreme caution." (Ex. H,

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FDA Guidance at § IV(G).)

II. Plaintiffs Do Not Contest That Dr. Betensky Did Nothing To Rule Out Plausible Alternative Explanations For Her Calculations.

Dr. Betensky's opinions are unreliable, notwithstanding her failure to consider critical data, because they are based on unsubstantiated assumptions about the reporting and detection of adverse events with IVC filters that are supported only by her impermissible *ipse dixit.* Bard explained in its Motion how comparison of SNF data to retrievable filters is an apples-to-oranges comparison. (*See* Mot. at 6.) Specifically, Bard detailed the significant differences between the permanent SNF and retrievable filters that Dr. Betensky compared, and how these differences can affect the way adverse events with these devices are detected and reported. (*Id.* at 2-4.) Plaintiffs do not address and therefore concede the existence and impact of these differences.

For example, Plaintiffs do not dispute that filter-related adverse events are often asymptomatic. Nor do they dispute that these asymptomatic events may be detected with greater frequency in patients with retrievable filters over similar patients with permanent filters owing to the differences in the design and use of these devices. (*See id.* at 2-3.) Plaintiffs similarly do not contest that there are potential differences in how frequently patients with permanent versus retrievable filters are followed, which may also lead to increased detection of these asymptomatic adverse events in patients with retrievable filters. (*See id.*) Further, Plaintiffs do not dispute that the dwell time of a filter in a given patient may also vary significantly between permanent and retrievable filters, which may result in increased detection of these asymptomatic adverse events in patients with retrievable filters. (*See id.*) Finally, Plaintiffs do not dispute that there may be differences in the reporting of adverse events, once detected, between retrievable filters and permanent filters, due to the publicity surrounding and related to ongoing litigation over retrievable filters. (*See id.* at 3-4, 12.) Nor do they contest that this may result in increased reporting of adverse events in patients with retrievable filters over similar

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patients with permanent filters.[9]

Dr. Betensky admitted that she did nothing to account for these differences. (*See* Ex. C, MDL Dep. Tr., 185:7-14 ("Q. What, if anything, did you do in this case to control for the possibility that individuals with asymptomatic adverse events that have retrievable filters only had those symptoms detected when the filter was removed? . . . A. I didn't have any information to do anything about that."); 189:7-10 ("A. I, I didn't take into account potential changes in reporting. Q. Based on litigation? A. Based on litigation."); 191:1-10 ("Q. It's entirely possible that the increases over time in reporting for the removable products that you noted were related to high profile litigation connected with the products, right? That's possible? . . . A. Anything is possible. I suppose. Q. You didn't do anything to rule out that possibility, did you? A. I don't have -- I didn't have the data to be able to do that kind of level of analysis.").)[10]

Furthermore, before she could draw unbiased inferences regarding an increased RR from her calculated RRRs, Dr. Betensky was "required" to apply certain "plausible" assumptions about the differential detection and reporting of adverse events between the retrievable filters and the SNF. (*See* Ex. E, Rebuttal Rep. at 1; Ex. C, MDL Dep. Tr., 96:9-11 ("in order to . . . draw inferences about the risk ratio from the reporting risk ratio, that's where assumptions are required.").) Otherwise, her opinions would be biased because the elevated risk she calculated could be due to the differences identified above, instead of, and entirely unrelated to, any *actual* increased risk. If her assumptions are

[9] Bard also identified the diminished likelihood that adverse events in patients with the permanent SNF would be reported over similar patients with retrievable filters based on the "Weber Effect," because the SNF had been on the market for over a decade before the retrievable filters. (*See* Mot. at 3-4.) Plaintiffs' own expert recognizes that the "Weber Effect" may impact her analysis, (*see* Ex. A, MDL Rep., at 13; Ex. B, Austin Dep. Tr., 110:11-14), undermining Plaintiffs' contrary argument. (*See* Pls. Br. at 14.)

[10] Although Plaintiffs broadly assert that Dr. Betensky identified and considered these limitations when interpreting her results, (*see* Pls. Br. at 3, 5-6), they do not contradict her clear testimony that she did nothing to account for these differences. Plaintiffs provide no authority to support their claim that the reliability of Dr. Betensky's opinion is *strengthened* by her recognition of these limitations. (*Id.* at 6 (emphasis added).) Instead, her failure to rule out these plausible alternatives is further evidence of the unreliability of her opinions.

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wrong, Dr. Betensky concedes "it wouldn't be appropriate to consider the reporting risk ratio as a risk ratio." (Ex. C, MDL Dep. Tr., 177:11-12.) As Bard explained in its Motion, to substantiate these assumptions requires an expert understanding of these complex medical devices and their use by the medical community. (*See* Mot. at 7.) Dr. Betensky admitted she lacks this specific expertise. (*See id*. at 7-10.)

Plaintiffs do not contradict this testimony, nor do they dispute that she failed to collaborate with anyone with such expertise. Instead, Plaintiffs claim that her expertise as a biostatistician somehow qualifies her to understand the differential detection and reporting of adverse events in these complex devices. (*See* Pls. Br. at 6 n.8.) This claim is without merit and is belied by Dr. Betensky's own testimony:

> Q. You're not a medical expert when it comes to what might impact the differential discovery and reporting of adverse events in a removable filter versus adverse events in a permanent filter?
>
> A. I'm not a medical expert in that.

(Ex. C, MDL Dep. Tr., 187:23 to 188:2.)

> Q. You're not an expert in the manner in which potential filter adverse events are detected, are you?
>
> A. Not in how they are clinically detected.

(*Id.* at 92:8-10.)

> Q. You're not an expert in the differences in how adverse events are clinically detected in retrievable filters versus permanent filters, right?
>
> A. Correct.

(*Id.* at 92:12-15.)[11]

Without an expert understanding of these differences to substantiate Dr. Betensky's assumptions, they are based on nothing more than her own *ipse dixit*. This is significant because, as Bard explained, and as Plaintiffs do not dispute, these assumptions are necessary to bridge the analytical gap between the RRR that Dr. Betensky calculated "and

[11] Contrary to Plaintiffs' assertion, (*see* Pls. Br. at 6 n.8.), none of the experts that relied on Dr. Betensky's report specifically accounted for these differences. (*Cf.* Pls. Ex. 13, ¶ 314; Ex. 14, ¶ 111; Ex. ¶ 33.)

the actual risks," RR, that she estimated. (Ex. B, Austin Dep. Tr., 134:25 to 135:14.)[12] "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Dr. Betensky's opinions of increased risk, RR, are connected to her calculated RRR only by her *ipse dixit.* Thus, this Court should "conclude that there is simply too great an analytical gap between the data and the opinion proffered," and exclude her opinions. *Id.*

CONCLUSION

For each of these reasons, Bard respectfully requests that this Court exclude the opinions of Dr. Betensky in their entirety.

RESPECTFULLY SUBMITTED this 18th day of October, 2017.

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[12] Plaintiffs similarly do not dispute that Dr. Betensky's RR is just a guess, a "crude estimate" of risk. (Ex. B, Austin Dep. Tr., at 106:20-25.) They do not dispute that she did not calculate an actual, quantifiable, increased risk or numerical value for RR. (*See* Mot. at 14-15.) She just inferred an increase without any real confirmation. Nor do Plaintiffs dispute that she has no rate of error and cannot calculate one. (*Id.* at 15.)

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of October 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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